

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE-OPELOUSAS DIVISION**

Charles LeBlanc, et al

Civil Action No. 04-0611

versus

Judge Tucker L. Melançon

Wyeth, Inc. et al

Magistrate C. Michael Hill

MEMORANDUM RULING AND ORDER

Before the Court is defendant Prescription Management Services, Inc.'s ("PMSI") Motion in *Limine/Daubert* to Exclude Testimony of Michael Corbett, Ph.D [Rec. Doc. 102] which plaintiffs oppose [Rec. Doc. 116]. For the reasons set out hereinafter, defendant's Motion [Rec. Doc. 102] will be DENIED WITHOUT PREJUDICE and subject to strict compliance by the attorneys for the parties with the Federal Rules of Evidence as set out below.

1. Background

Plaintiffs claims against PMSI arise from Charles LeBlanc's ingestion of the prescription medication Cordarone/Amiodarone, an anti-arryhythmic drug used to treat irregular heartbeats.¹ Plaintiffs allege that defendant PMSI caused their damages by negligently failing to warn LeBlanc or his prescribing physicians that his dosage was excessive and filling LeBlanc's prescription of the drug in excess of the manufacturer's dosage and duration instructions. Plaintiffs indicate that they engaged

¹Amiodarone is the generic version of the brand name drug Cordarone.

Michael D. Corbett, Ph.D., a toxicologist, to review the case and give an expert opinion as to the etiology of LeBlanc's pulmonary condition relative to the dosage of Amiodarone that LeBlanc had been prescribed [plaintiffs' Memorandum in Opposition to defendant's *Daubert* Motion, Rec. 116]. Defendant moves the Court to disallow Dr. Corbett's testimony because of his lack of training, education and experience to the specific drug at issue [defendant's Memorandum in Support of *Daubert/Limine* Motion, Rec. Doc. 102].

II. Analysis

“The admission of expert testimony is reviewed for abuse of discretion.” *U.S. v. Fullwood*, 342 F.3d 409, 412 (5th Cir. 2003). Applying this standard, the Fifth Circuit has “recognized that district courts are given ‘wide latitude in determining the admissibility of expert testimony, and the discretion of the trial judge ... will not be disturbed on appeal unless manifestly erroneous.’” *Wilson v. Woods*, 163 F.3d 935, 936 (5th Cir. 1999) (citation omitted). “The district court's role in determining admissibility of scientific testimony under Fed.R.Evid. 702 is that of gatekeeper.” *Id.*, citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786 (1993). “Rule 702 sets the admission standard: If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an

expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the witness has applied the principles and methods reliably to the facts of the case.” *Id.* In *Daubert*, the Supreme Court concluded that under Rule 702, a “trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Id.* at 589, 113 S.Ct. at 2795. The Court noted that “this entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology can properly be applied to the facts in issue.” *Id.* at 592- 93, 113 S.Ct. at 2796.

The Court in *Daubert* stated several key factors for district courts to consider in assessing expert testimony: (1) whether the expert's hypothesis can be and has been tested; (2) whether the hypothesis has been subjected to peer review or publication; (3) the known or potential rate of error; and (4) whether the theory is generally accepted within the relevant community. *Id.* at 593-94, 113 S.Ct. at 2796-97. The Court stressed that the inquiry should be flexible and focused solely on principles and methodology, not on the conclusion generated. *Id.* at 594-95, 113 S.Ct. at 2797.

At issue are the qualifications of Dr. Corbett and the reliability of his causation opinions. Dr. Corbett's July 30, 2006 report [plaintiffs' Response, Rec. Doc. 116, Exh. 3] includes the following opinions: that LeBlanc suffered a debilitating illness as a result of the toxic effects of Amiodarone, of which toxicity to his lungs was the most significant; that LeBlanc was treated with an excessive, inappropriate dose of the drug; that the temporal relationship of his treatment with the drug was consistent with Amiodarone being the cause; that it is unlikely that LeBlanc he would have suffered Amiodarone toxicity had he been treated with an acceptable dose; that the physician who prescribed the Amiodarone made a mistake in selecting the dosage and is responsible for its adverse effects in LeBlanc; that LeBlanc suffered an invasive and debilitating effect of the overdose in addition to immediate toxic effects; that the Amiodarone overdose caused a persistent deficit in LeBlanc's pulmonary function that is unlikely to improve; and that LeBlanc will be at risk for the development of pulmonary fibrosis for the rest of his life.

Defendant argues that Dr. Corbett is not qualified to give these opinions at trial because, prior to being retained as an expert in this matter, he had no consulting experience regarding Amiodarone and that he has no medical degree nor any clinical training in the use of Amiodarone [defendant's Memorandum,

Rec. Doc. 102, pp. 4-5]. Defendant submits that, in order to give his expert opinion, Dr. Corbett “cherry picked” the literature on Amiodarone, reading those articles he felt supported plaintiffs’ allegations [Id. at p. 5]. Defendant further challenges Dr. Corbett’s methodology, arguing that he failed to rule out Plavix, a drug being taken by LeBlanc on his late December, 2002, early January, 2003 hospital admission with “similar known risks of pulmonary complications” or LeBlanc’s pre-surgery lung disease as possible causes of his alleged lung condition [Id. at pp. 5-6]. Defendant further argues that Dr. Corbett dismisses the objective findings of Dr. Ronald A. Welsh that LeBlanc suffered from an idiopathic lung disease of unknown etiology and fails to rule out the possibility that LeBlanc suffered a post-cardiac surgery infection that caused his pulmonary complaints [Id. at pp. 6-7]. Defendant also contends that the only objective evidence supporting Dr. Corbett’s opinion is a January, 2003 “low DLCO” result, while Dr. Corbett admitted that he lacked a “baseline” to compare and LeBlanc’s treating physicians have testified that he had a low oxygen saturation before surgery and any ingestion of Amiodarone [Id. at p. 7].

As to the *Daubert* factors, defendant submits that plaintiffs must show both general causation, that the alleged toxin is capable of the injuries of the kind allegedly suffered; and specific causation, that is, the toxin caused the plaintiff’s

alleged injuries, and that the *Daubert* analysis applies to plaintiff's expert's methodology in providing reliable opinions on both general and specific causation, relying on *Bonner v. ISP technologies, Inc.*, 259 F.3d 924 (8th Cir. 2001) and *Wright v. Willamette Industries, Inc.*, 91 F.3d 1105 (8th Cir. 1996). Defendant contends that the proffered testimony fails *Daubert* factors as it has not been tested; has not been subjected to peer review; was developed solely for this litigation; and that Dr. Corbett is unqualified to give the testimony as he is not a medical doctor.

Plaintiffs respond that, based on Dr. Corbett's education, experience and research, that Dr. Corbett is well qualified to give his expert opinion on the biochemical toxicity properties of Amiodarone, and that, although defendant accuses Dr. Corbett of "cherry picking" the literature, neither defendant nor its expert, Raymond D. Harbison, MS, Ph.D., have cited to scientific authority that disputes Dr. Corbett's opinions or the scientific journals that Amiodarone can cause pulmonary toxicity, and show that LeBlanc's treating pulmonologist in addition to plaintiffs' medical experts agree on LeBlanc's diagnosis of pulmonary toxicity [plaintiffs' Response, Rec. Doc. 116, p. 3]. Plaintiffs reference the FDA required warning:

Cordarone is intended for use only in patients with the indicated life-threatening arrhythmias because its use is accompanied by substantial toxicity. Cordarone has several potentially fatal toxicities, the most important of which is pulmonary toxicity (hypersensitivity pneumonitis or interstitial/alveolar pneumonitis) that has resulted in clinically manifest disease at rates as high as 10 to 17% in some series of patients with ventricular arrhythmias given doses around 400 mg/day, and as abnormal diffusion capacity without symptoms in a much higher percentage of patients. Pulmonary toxicity has been fatal about 10% of the time.

[Id.]. As to defendant's objections to Dr. Corbett's scientific method, plaintiff submits the testimony of their expert pulmonologist that the scientific method was employed when the drug was brought on the market by the FDA [Id. at p. 4]. As to defendant's argument that Dr. Corbett failed to rule out the drug Plavix as a possible cause of LeBlanc's complaints, plaintiffs respond that Dr. Corbett's report included the explanation that the diagnosis of Amiodarone pulmonary toxicity is a diagnosis of exclusion and that Plavix adverse reactions are not serious ones [Id. at p. 6]. As to defendant's argument that Dr. Corbett's theory has not been tested, plaintiff argues that defendant seems to suggest that LeBlanc be re-challenged with Amiodarone at a lower dose which would be irresponsible [Id. at 6-7]. In sum, plaintiffs argue that, considering the statements of all of the witnesses, with the exception of defendant's expert Dr. Harbison, who have

rendered opinions in the case, that the defendant's reliance on Dr. Harbison's statement's regarding Dr. Corbett's methodology is misplaced.

The Court having considered the record in its entirety finds that Dr. Corbett's testimony will assist the trier of fact in understanding the nature and characteristics of Amiodarone in connection with the allegations made by plaintiffs. Dr. Corbett's *Curriculum Vitae* ("CV") reflects that he is graduate of the University of Kansas with a Doctor of Philosophy in Medicinal Chemistry which he indicates in his deposition is an area dedicated to the development of new drugs, which includes not only the design of new chemical structures but also consideration of metabolism, biological disposition and toxicology [Corbett Depo., Rec. Doc. 102, Exh. 3]. Dr. Corbett's CV and deposition testimony also reflect that he has been employed as a Professor of Biochemical Toxicology and Adjunct Professor of Pharmacology at the School of Medicine, University of Florida; Professor of Chemical Toxicology and Carcinogenesis at the University of Nebraska Medical Center and as an independent consultant in Chemical Toxicology. Dr. Corbett indicates that he conducted research in the fields of biochemical toxicology and chemical carcinogenesis until his retirement from academia in 1998, has received funding through research grants from the National Institutes of Health and has published 67 peer-reviewed scientific articles during

the period 1972-94. Dr. Elliott indicates that, in order to arrive at his opinions, he examined Mr. LeBlanc's medical records and the April 25, 2006 deposition of Dr. Fei, LeBlanc's treating physician and also details his method of choice of the scientific and medical literature which he reviewed in order to reach his opinions.

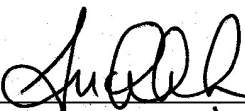
At this juncture, the Court concludes that Dr. Corbett is qualified to give expert opinions as a toxicologist and that his methodology has been properly supported. Plaintiff will be required to establish the proper evidentiary foundation for any expert testimony offered at trial. The Court will require Dr. Corbett to testify in person at trial. Defense counsel shall be free to offer objection to any question posed by plaintiff's counsel, and the Court will rule on the objections either in or out of the presence of the jury as may then be appropriate.

Accordingly,

IT IS ORDERED that defendant's Motion in *Limine/Daubert* to Exclude

Testimony of Michael Corbett, Ph.D [Rec. Doc. 102] is **DENIED WITHOUT PREJUDICE.**

Thus done and signed this 13th day of July, 2007 at Lafayette, Louisiana.



Tucker L. Melançon
UNITED STATES DISTRICT JUDGE